IDPH IOWA Department of PUBLIC HEALTH
Protecting and Improving the Health of Iowans
Kim Reynolds, Governor | Adam Gregg, Lt. Governor | Kelly Garcia, Interim Director

COVID-19 Therapeutics Information Brief

February 23, 2022

Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Therapeutics Information

- Therapeutic Reporting Reminder
- Reporting Wastage Guidance
- Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- FDA Announces Emergency Use Authorization for Eli Lilly's bebtelovimab
- Bamlanvimab/Etesevimab and REGEN-COV No Longer Authorized for Use by FDA
- Return of bam/ete and REGEN-COV NOT Recommended
- Disposal of Extra Doses of Nirmatrelvir from Blister Packs for Patients with low eGFR
- COVID-19 Treatment Guidelines When There Are Logistical or Supply Constraints
- Redistribution Requests for Therapeutics
- Weekly Allocations Cadence for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- Oral COVID-19 Therapeutics Pharmacy Coverage Informational Letter from Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)
- Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
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Therapeutic Reporting Reminder and Reporting Wastage Guidance

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements. Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products.

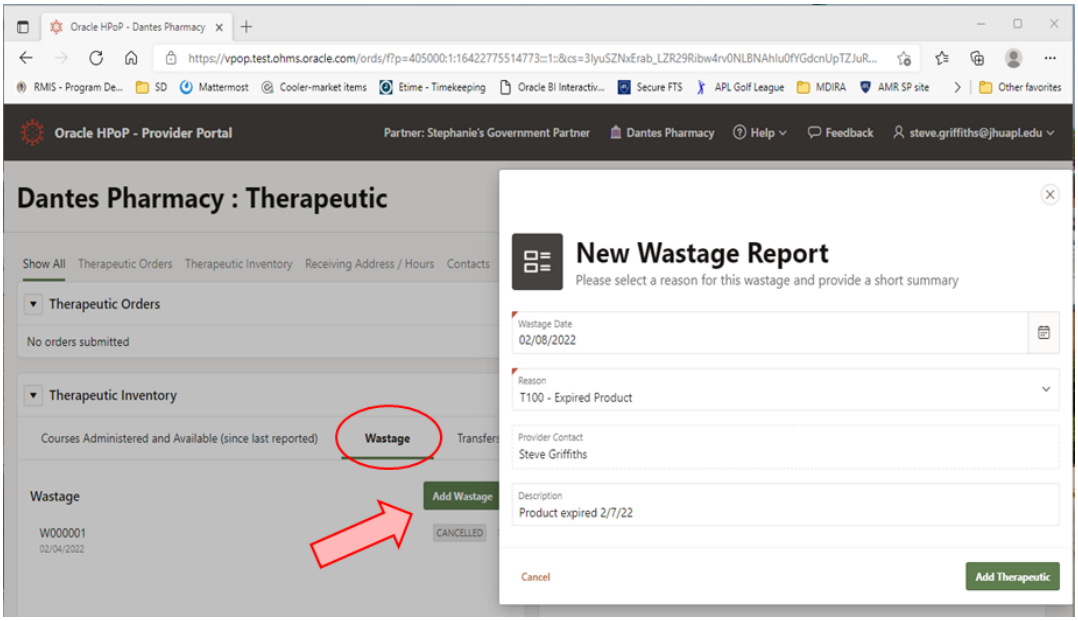
Reporting requirements are as follows:

- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir) and the new monoclonal antibody (Bebtelovimab): Report on-hand and usage data **daily** in HPoP. If you need assistance with HPoP, please contact C19therapeutics@idph.iowa.gov.

Reporting Wastage

In the Provider or Partner Portal, a new tab has been added in the Therapy Inventory section – Wastage. Wastage will be reported for all therapeutic products except Sotrovimab. The following steps outline the reporting of wastage of COVID-19 Therapeutics in HPoP:

- Choose wastage, then select the green "Add Wastage" button. A blank report appears.
- Enter the wastage date, the reason for the wastage (expired, damaged, temp excursion, or other).
    - A provider contact may be chosen, or is predetermined.
    - A description can be added.
- Upon selecting Add Therapeutic, a second window will open allowing details for each line in the wastage report to be entered. Select the therapeutic from drop down, enter the number of courses, a lot number and the lot expiration date.



Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

	Iowa Statewide Allocations for the week Monday, January 31, 2022 - Sunday,February 6, 2022			
	mAbs	Oral AVs		PrEP
Bebtelovimab	Sotrovimab	Mulnupiravir	Paxlovid	EVUSHELD
385 courses	**414 doses**	**2688 courses**	**1140 courses**	**480 doses**

Therapeutic product requests from Iowa healthcare providers continue to greatly exceed the number of therapeutic courses allocated to Iowa by the federal government. HHS has clearly stated the intent to decrease the allocation of therapeutics, specifically monoclonals, as Omicron becomes dominant across states. Iowa continues to see a decrease in allocation numbers from the federal government for BAM/ETE and REGEN-COV therapeutics. Please refer to the below talking points to ensure healthcare providers are up-to-date with the current therapeutics allocation process.

- The minimum order quantity for Molupiravir is 24 courses.
- The Iowa Department of Public Health (IDPH) is working to prioritize allocations of therapeutic products based on the regional trends of the variants.
- County by county variant rates *are not* being considered in therapeutic requests due to available data.
- **Allocations will not include bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **Healthcare providers should NOT expect to receive regular (or any) allocations of therapeutic products.**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Therapeutic Information Brief will continue to provide the most up-to-date information regarding the availability of therapeutic products and ordering cadence.
- The Department of Health and Human Services has released a COVID-19 Therapeutics locator. Monoclonals are not well populated yet largely because of availability across the state/nation.
    - The locations displayed in the locator are based on stock on hand as reported by the location and are not a guarantee of availability.
    - Locations that report fewer than 5 courses of the selected therapeutic are not displayed. All therapeutics identified in the locator must be used in alignment with the terms of the respective product's EUA.
    - **This therapeutics locator is intended for provider use, as the included therapies require a prescription by a licensed and authorized provider. Patients should not contact locations directly.**

FDA Announces Emergency Use Authorization for Eli Lilly's bebtelovimab

The FDA announced emergency use authorization for Eli Lilly's bebtelovimab. Bebtelovimab is a monoclonal antibody product now authorized during this pandemic for the treatment of mild to moderate COVID-19 in adults and certain pediatric patients who are at high risk for progression to severe COVID-19, including hospitalization or death and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

- Bebtelovimab is administered as an intravenous injection.
- The U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response will oversee the fair and equitable allocation and distribution of this product.

- Bebtelovimab may only be used for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg):
    - With positive results of direct SARS-CoV-2 viral testing, **and**
    - Who are at high-risk for progression to severe COVID, including hospitalization or death, **and**
    - For whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate
- Bebtelovimab usage must be reported in HPoP daily

Resources:

- Bebtelovimab EUA Letter of Authorization
- Fact Sheet for Healthcare Providers
- Fact Sheet for Patients, Parents and Caregivers
- Frequently Asked Questions for Bebtelovimab

Bamlanvimab/Etesevimab and REGEN-COV No Longer Authorized for Use by FDA

The FDA updated the Emergency Use Authorization (EUA) fact sheets for Lilly's bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV).

- Limits use to only when a patient is likely to have been infected with or exposed to a variant susceptible to these treatments
- Data show treatments highly unlikely to work against Omicron variant
- Treatments not currently authorized for use in any U.S. states, territories, jurisdictions
- Products must be used in accordance with EUA guidance

This follows action last week by the National Institutes of Health (NIH) to update its clinical guidelines to recommend against the use of bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) as real-time testing to identify rare, non-Omicron variants is not routinely available. The Omicron is the dominant variant nationally and is greater than 99% (CDC Nowcast data). Alternative therapeutics remain available:

- Sotrovimab, Evusheld, Paxlovid, Molnupiravir – available through HHS allocations
- Veklury (remdesivir) – available commercially

Return of bam/ete and REGEN-COV NOT Recommended

Product return of bam/ete and REGEN-COV is ***NOT*** recommended as any returned product has to be destroyed. The COVID-19 environment remains dynamic and these products may be effective against future variants. Current supplies of bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV) should be retained by healthcare providers for potential use for other COVID variants. If healthcare providers have storage concerns or challenges, consider transferring products to another location/site in the region or health system.

If product must be returned, please follow the guidance below:

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- For bam/ete, see The Lilly Return Goods Procedure; detailed guidance can be found at: https://www.lillytrade.com/
- For REGEN-COV, call 844-734-6643
- Note: Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's SOP

Disposal of Extra Doses of Nirmatrelvir from Blister Packs for Patients with low eGFR

Per Dear HCP Letter endorsed by the FDA, in reference to moderate renal impairment dosing adjusted to 150 mg nirmatrelvir with 100 mg ritonavir taken twice daily for 5 days: "Pharmacists should discard the removed tablets per state requirements or local guidelines." It is recommended providers dispose of the medication via the workflows used to dispose of expired or other waste purposes. The HCP letter and Pharmacist Instructions are available at: https://www.covid19oralrx-hcp.com/resources.

COVID-19 Treatment Guidelines When There Are Logistical or Supply Constraints

The purpose of this interim statement is to provide guidance on which individuals might receive the greatest benefit from anti-SARS-CoV-2 therapeutics for treatment or prevention.

Prioritization:

- Treatment of COVID-19 over post-exposure prophylaxis (PEP) of SARS-CoV-2 infection
- Treatment of COVID-19 in unvaccinated or incompletely vaccinated individuals with clinical risk factors for severe illness and vaccinated individuals who are not expected to mount an adequate immune response
- Use of tixagevimab plus cilgavimab (Evusheld) as pre-exposure prophylaxis (PrEP) for severely immunocompromised individuals over moderately immunocompromised individuals

Tier	Risk Group
1	Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); *or* Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
2	Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
3	Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.
4	Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/

Redistribution Requests for Therapeutics

Requests have been received regarding redistribution of monoclonal antibodies, evusheld and antivirals. Healthcare providers wanting to redistribute antivirals (Paxlovid, Molunpiravir) and pre-exposure prophylaxis (Evusheld) must email the IDPH Therapeutics Call Center at C19Therapeutics@idph.iowa.gov to initiate the redistribution process. **Do not redistribute any doses or courses of antivirals (Paxlovid, Molunpiravir) and pre-exposure prophylaxis (Evusheld) without contacting the Therapeutics Call Center prior to physically transferring.** At this time, monoclonal antibodies do not require IDPH approval for redistribution. Healthcare providers may continue the current practice of monoclonal antibodies redistribution. In the future, monoclonal antibodies may be incorporated into this redistribution policy.

Oral COVID-19 Therapeutics Pharmacy Coverage Informational Letter from Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

The link below is to an informational letter updating providers regarding the appropriate billing and coding fees for the use of two oral antivirals for treatment of COVID-19 under an emergency use authorization (EUA).

- Oral COVID-19 Therapeutics Pharmacy Coverage Informational Letter, January 2022

The link below references coverage of over the counter anti-viral information on the HRSA website and correlating FAQs.

- https://www.hrsa.gov/CovidUninsuredClaim
- https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions

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Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals

Local Public Health Agencies and Hospital Partners should refer to the Iowa Health Alert Network (HAN) Therapeutics folder-partner list for the spreadsheet listing the facilities that have been allocated therapeutics for each type of product.

COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center -** IDPH has established a COVID-19 Therapeutics Call Center. To reach the COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** IDPH has set up a COVID-19 Therapeutics Email to respond specifically to questions from healthcare providers regarding COVID-19 therapeutics. Therapeutic questions can be emailed to: C19Therapeutics@idph.iowa.gov
- NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- **COVID-19 Therapeutics Website -** IDPH is in the process of updating the COVID-19 Therapeutics website with additional resources. Information will be shared as soon as it is available.

COVID-19 Therapeutics Table

	mAbs		Oral Antivirals		PrEP
Products	**Sotrovimab (GSK)**	**Bebtelovimab (Eli Lilly)**	**Molnupiravir (Merck)**	**Paxlovid (Pfizer)**	**Tixagevimab/Cilgavimab (EVUSHELD)**
Authorized Use(s)	Treatment of mild to moderate symptoms	Treatment of mild to moderate symptoms	Treatment of mild to moderate symptoms	Treatment of mild to moderate symptoms	Pre-exposure prevention for immunocompromised individuals
Age Eligibility	Ages 12 years and older	Ages 12 years and older	Ages 18 and older	Ages 12 years and older	Ages 12 years and older
Weight Eligibility	88 pounds or more	88 pounds or more	No weight requirement	88 pounds or more	88 pounds or more
Other Criteria for Treatment	Test Positive for SARS-CoV-2 Be within **10** days of the start of symptoms Not be hospitalized	Test Positive for SARS-CoV-2 Be within **7** days of the start of symptoms Not be hospitalized **Not require oxygen and/or respiratory support**	Test Positive for SARS-CoV-2 Be within **5** days of the start of symptoms Not be hospitalized	Test Positive for SARS-CoV-2 Be within **5** days of the start of symptoms Not be hospitalized	**Not currently infected with SARS-CoV-2** Have not had a known recent exposure to an infected individual with SARS-CoV-2
Other Criteria for Prevention					Must have moderate to severe immune compromise due to a medical condition diagnosed by a health care provider
Letter of Authorization	Sotrovimab Letter of Authorization (EUA)	Bebtelovimab Letter of Authorization (EUA)	Molnupiravir EUA Letter of Authorization	Paxlovid EUA Letter of Authorization	Evusheld EUA Letter of Authorization (EUA)
EUA Fact Sheet	Sotrovimab Provider Fact Sheet	Bebtelovimab Provider Fact Sheet	Molnupiravir Provider Fact Sheet	Paxlovid Provider Fact Sheet	Evusheld Provider Fact Sheet